REMARKS

This communication responds to the final Office Action of August 24, 2007.

In this response, claims 4 and 20 are amended. The claim modifications do not add new matter.

Reconsideration and withdrawal are requested.

Rejection Under 35 U.S.C. § 102

Claims 2, 4-6, 8-13, 18, 20-26 are rejected under 35 U.S.C. § 102(b) as being anticipated by Yasumichi (JP P2000-84078A). The Office asserts that Yasumichi "discloses in figures 1 and 4-8 a cannula system comprising a cannula support comprising a thread turning in a first direction (10, 11) and another thread turning in the second, generally opposite direction (15,16); and a protective cap 12 for covering a point of a needle having a thread (18, 19) engageable with said thread turning in said second generally opposite direction, at least one latching element 13 arranged on the cannula support, the cap comprising a complementary latching element 17 and an injection device 1 having a thread (7,8) engageable with said thread turning in the first direction. With respect to claim 2, wherein the term "inner" is seen to be proximal and the term "outer is seen to be distal."

The rejection is traversed for at least the following reasons.

As amended hereby, claim 4 requires, in part:

> a cannula support comprising a thread turning in a first direction and another thread turning in a second, generally opposite direction, the cannula support having an outer side and an inside, said threads arranged least on the outer side of the cannula support;

Specific support for this amendment is found in the specification at, for example, paragraph [0013] and is illustrated in the drawings as filed, e.g. Figs. 1-5, showing the relationship of the elements.

The Office has misrepresented Yasumichi. First, the elements illustrated at (10,11), (15,16) and (18,19) are not threads. Specifically, elements 10, 15 and 18 are inclined planes. Elements 11, 16, and 19 are "level difference sections" as identified in the patent and may be equated with stops. This is clearly shown in the figures and, especially, Figure 8 which illustrates the lack of threads.

Further, as amended hereby, claim 4 requires that the threads are on the inner perimeter or the outer perimeter of the cannula support. Applicants note that thread is defined as:

> **thread** (SCREW) noun [C]: a continuous raised line, such as the one which goes around the outside of a screw or bolt or the inside of a hole.
> Cambridge International Dictionary of English, © Cambridge University Press 2007.

As illustrated in Yasumichi, the level difference sections are not on the inner perimeter or outer perimeter of the cannula support but are terminal projections on the injector. The level difference illustrated in Yasumichi are clearly not threads nor are they disposed on the inner or outer perimeter of the holder. Therefore, Yasumichi cannot anticipate the instant invention.

Further, the inclined plane and level difference section cannot be considered as threads, because the elements cannot be tightened as threads are tightened and thus, could not act such that "the outer protective sleeve 4 is released from the cannula support 1 by continuing the turning movement, such that the outer protective sleeve can be unscrewed from the cannula support 1." See, paragraph [0031]. Thus, the elements identified by the Office, (10,11), (15,16) and (18,19) are not threads literally, figuratively or functionally. For this reason, at least, the rejection is unfounded and should be withdrawn.

With respect to claims 9-13 & 18, the Office states that Yasumichi discloses "latching element 13 on the cannula support and a corresponding latching element 17 on the cap, wherein the device is fully capable of having a releasable manner with element 17 on the cap, wherein the device is fully capable of having a releasable manner with element 17 not being pushed past element 13 to provide an easier cover, while if the element 17 is pushed past element 13 would create a non-releasable manner."

This rejection is traversed for at least the following reasons.

The Examiner's characterization of Yasumichi is disingenuous. As illustrated in Yasumichi, elements 17 and 13 are "protruding lines". When opposing elements 17 and 13 are not pushed past each other, they are not latched, i.e. there can be no release if the elements are not coupled.

Claim 9 requires, in part, that "the protective cap can be *coupled to the cannula support* in such a way that there is no connection between the latching elements."

This arrangement is clearly illustrated in the drawings, e.g., FIG. 1 and FIG. 2. Further, applicants point out that the element is a "protective cap" and that the arrangement described by the Office where there is *no connection* between the cap and the cannula support could hardly be considered protective. For this reason, at least, the rejection should be reconsidered and withdrawn.

With respect to claims 20-26, the Examiner states that "the reference disclosing a cannula system comprising a Cannula support comprising a first portion 5 having a first diameter, a second portion having a second diameter greater than the first diameter the second portion comprising an exterior thread which is seen to be a distal thread (15,16), turning in a first direction and an interior thread, seen as a proximal thread (10,11), turning in a second, generally opposite direction, . . ."

As disused above, Yasumichi does not disclose threads. The elements cited by the Examiner are neither literally or operationally threads. Further, claim 20, from which claims 21-26 depend, requires that the threads are interior threads and exterior threads. For this reason alone, the rejection should be withdrawn.

Further, the Examiner represents the elements (15, 16) and (10,11) as distal and proximal, respectively, while the claim requires that the cannula support include a first portion with a first diameter, a second portion with a second diameter and that the interior and exterior thread be displaced upon the second portion. This arrangement is not possible in Yasumichi because (15,16) cannot be disposed proximally while (10, 11) are disposed distally on the needle support

and still comprise internal and external threads on a second diameter of a second portion of the instant cannula support as required by the claim, not least of all because the diameters of (15, 16) and (10, 11) are different. The Examiner cannot have the elements be both proximal and distal and also interior and exterior. Thus, at least for this reason, the rejection should be withdrawn.

Rejection Under 35 U.S.C. § 103

Claim 7 is rejected under 35 U.S.C. § 103(a) over JP P2000-84078A as applied to claim 4 above and further in view of Kakiuti (EP 749760B1). The rejection of claim 4 over Yasumichi traversed above, and the addition of Kakiuti cannot render dependent claim 7 obvious because Kakiuti does not remedy the defects of Yasumichi.

Claims 14-17 are rejected under 35 U.S.C. § 103(a) over JP P2000-840748A as applied to claim 9 and further in view of MPEP 2144.04 VI Section B.

Claims 14-17 depend from claim 9. The rejection of claim 9 over Yasumichi is discussed above. Further, the addition of MPEP 2144.04 VI, Section B does not rectify the deficiencies of Yasumichi. In addition, the Examiner misrepresents MPEP 2144.04 VI, Section B. The case referred to (*In re Harza*) characterizes the duplication of parts upon a single element. Thus, the case in question provides foundation for the finding a plurality of ribs on a seal with the prior art only explicitly teaching one rib on a seal. In the case of instant claims 14-17, the latching elements required are found on the support, the cap, and the pen. The Examiner is using MPEP 2144.04 VI, Section B to justify reading into the prior art elements which are not there in the first place not, as the Examiner asserts, merely duplicating the element disclosed. As taught by the court "the mere duplication of parts has no patentable significance unless a new and unexpected result is produced . . The other limitations defined by claim1 are manifest in Gardner." In re Harza, 274 F.2d 669, 774. Thus, the court emphasizes that there may be license to duplicate parts but, first, the limitation must be present. In this case, the Examiner is using Harza to provide license to read in limitations that are wholly lacking. For at least this reason the rejection should be withdrawn.

Claim 19 is rejected under 35 U.S.C. § 103(a) over JP P2000-84078A in view of Sellar (U.S. Patent 1,050,042) and further in view of Kakiuti (EP 0749760B1). As discussed above, Yasumichi does not teach threads. The location of the elements asserted by the Examiner is incorrect to utilize the invention as required. Kakiuti does not rectify the deficiencies of Yasumichi. Sellar does not remedy the deficiencies of Yasumichi and Kakuiti.

Claim 19 requires a needle support including a cam, an inside surface with a thread for coupling the injection device, an outer protective cap comprising a left-handed thread and a cavity on an inside surface, the needle support comprising a complementary counter thread whereby the outer protective cap and the needle support may be releasably connected to each other such that the cam on the needle support is received in the cavity of the outer protective cap. As defined by the Examiner, the cam (13) of Yasumichi helps secure the inner cap to the needle support. As discussed, claim 19 requires the cams be arranged to as to be received in the outer cap. This arrangement manifestly illustrates that even if the elements of claim 19 were present in the combination asserted by the Examiner, which they are not, the combination would not work as required by the claims because the cams of Yasumich interact with the inner protective cap, not the outer one as required. Thus, the rejection of claim 19 should be withdrawn.

Conclusion

This response is being filed on or before December 24, 2007, with the required fee for a one-month extension of time, making it timely. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application now stands in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

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